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Use of External Fixator as the Definitive Treatment option in fracture management During Covid-19 Pandemic: A Prospective cohort study

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ABSTRACT

Open fractures are frequently encountered in musculoskeletal injuries and are frequently accompanied by the complication of infection. In this exceptional circumstance the supplementary rates of infection exacerbate the strain on the healthcare system that is already compromised. The primary objective of this study is to investigate the impact of the COVID-19 pandemic on the management of open fractures. Prospective Observational Study. In 50 patients 18 years or older, radiologically confirmed fracture that can be fixed definitively with external fixator, Excluded patients were medically unfit, conservatively treatable and unable to give written consent. With Index Medical College, Hospital and Research Centre, Indore, Madhya Pradesh Institutional Ethics Committee approval. The study included eligible patients. We got informed consent in writing. A total of 50 patients with open fractures met the inclusion criteria. In the present study, around three-fifth (62%) study subjects were males and remaining two-fifth (38%) were females. Around one-half (54%) of study subjects in our study belonged to age group of 21-40 years while one-fourth (26%) patients were in the age group of 41-60 years. Elderly patients (those aged >60 years) comprised 20% of study population. Mean age of study participants was found to be 43.60 years. In our study, 46% of fractures were of radius which were followed by tibial fractures which comprised of around one-fourth (26%). Remaining sites of fracture included humerus (16%), femur (8%) and calcaneum (6%) respectively. Radiological outcome at the end of 6 months showed that 82% patients had union while 10% patients were found to have malunion and 8% as non-union. In CORONA, external fixators can manage and treat fractures minimally invasively, according to our study. Radiological status assessment showed good union after follow-up. After follow-up, VAS, range of motion and power improved. For extensive evaluation as standard management, this technique needs a larger sample size. Restoring range of motion and power with an external fixator may be minimally invasive.

INTRODUCTION

The management of open fractures during the COVID-19 pandemic has faced challenges, particularly in highly populated nations such as India, where there is a rapid increase in cases^[1]. In the current challenging circumstances, orthopaedic surgeons globally are confronted with a multifaceted predicament concerning treatment prioritization, injury-related consequences, the safety of medical personnel, patients, and the operating surgeon, as well as the allocation of resources for patient triage^[2]. Efforts are currently underway to address this unforeseen and exceptional issue by the implementation of established and proven conservative management techniques, as well as the optimal utilization of existing resources^[3]. Moreover, the implementation of an evidence-based strategy on a case-by-case basis might effectively mitigate potential difficulties, hence mitigating the exacerbation of the current COVID-19 situation^[4].

Orthopedic injuries such as open fractures, unreduced dislocations, crush injuries, traumatic amputation, compartment syndrome, multiple long bone fractures, and septic arthritis are all characterized by their urgent and emergent nature, requiring immediate attention and intervention^[5]. Among these injuries, open fractures are a prevalent type of musculoskeletal injury and frequently present complications in the form of infection, resulting in extended periods of morbidity for the patient. The user has provided a numerical range of^[6,7]. A significant number of these cases pose obstacles in terms of therapy, as indicated by the existing resources and exhibit variations that are specific to each individual instance^[8]. While the utilization of an evidence-based strategy can potentially mitigate management concerns on an individualized basis the establishment of universally accepted treatment protocols or standards for the management of numerous open fractures continues to be a subject of controversy^[4].

The inadequate management of open fractures is linked to compromised bone healing, complications in wound healing and elevated rates of infection. These factors contribute to the development of long-term disability, resulting in extended distress for the affected patient^[6,7]. Moreover, the substantial prevalence of neglected trauma cases in India, resulting from delayed presentation, misdiagnosis, ineffective conservative treatment and limited resources at healthcare facilities, exacerbates the strain on hospital resources during the ongoing COVID-19 pandemic. In this study, we aim to investigate the effects of a particular drug on the growth of Furthermore the inclusion of non-specialist physicians, unqualified practitioners, osteopaths, provision of treatment in substandard operating

conditions, the shutdown of outpatient departments, the transformation of trauma centers into exclusive COVID facilities the placement of anesthesiologists in different ICU wards the closure of elective operating theaters, and the redistribution of existing personnel to COVID-related responsibilities exacerbate the strain on an already overwhelmed healthcare system^[1,9]. Internationally, healthcare systems across even the most affluent nations are already experiencing fragility, indicating the necessity of reevaluating existing treatment methods in order to enhance the triage of orthopaedic trauma^[10].

With the objective of analysing and understanding the present scenario, comprehending the current acute management of open fractures, this text centres on focussing on large number of those controversial discussions. With the aim of summarizing the present understanding of best evidence for the acute treatment of open fractures, this supplement focuses on addressing many of those critical controversies. This paper will add to the debate and hopefully provide a framework for decision making in open fracture care during this difficult time.

MATERIALS AND METHODS

This is a Prospective Observational Study carried out in a tertiary care setup. A total 50 patients aged 18 years and above, Radiological confirmed fracture that can be fixed definitively using external fixator, Fresh and open fracture were included while patient who were medically unfit, can be treated conservatively and whom are not ready to give to written consent were excluded. After obtaining the approval from Institutional Ethics Committee of Index Medical College, Hospital and Research Centre, Indore, Madhya Pradesh. Patients fulfilling the inclusion criteria were selected to participate in the study. Written and informed consent was taken. Proforma fracture examination was filled, and data was collected in Department of orthopedics at Index medical college. Patients were clinically examined and investigations were done. Digital AP and Lateral X-rays of the fracture site, CBC, Random Blood sugar, Blood grouping and Rh. Typing, HbsAg, HIV Elisa, Bleeding and clotting time, RT-PCR sampling, CHEST X-RAY PA view and ECG. Outcomes were assessed based on the following parameters. Pain, Muscle Power, Range of Motion, Radiological sign of union. All collected data was documented, tabulated and analysed.

RESULTS

Table1 shows the sociodemographic and clinical profile of study participants. Out of total, 62% (31) were males and 38% (19) were females. We discovered that roughly half (54%) of the study participants were

Table 1: Sociodemographic and clinical profile of study participants

	Gender	Frequency (N = 50)	Percentage
Gender	Male	31	62
	Female	19	38
Age	21-40	27	54
	41-60	13	26
	>60	10	20
Site of Fracture	Radius	23	46
	Tibia	12	24
	Humerus	8	16
	Femur	4	8
	Calcaneum	3	6

Table 2: Distribution of study participants according to fracture status at end of 6 months

Fracturestatus	Frequency (n)	Percentage
Union	41	82
Non-union	04	08
Malunion	05	10
Total	50	100

Table 3: Descriptive statistics for different characteristics

Characteristics	Mean	Standard Deviation	Seof Mean
Time of presentation (in hrs)	2.30	1.26	0.17
Range of motion	18.70	14.35	2.02
Power	1.22	1.03	0.14
VAS at presentation	6.18	1.45	0.20
VAS at 24 hrs	4.94	1.09	0.15
VAS at 1 month	2.38	1.42	0.20
VAS at 3 months	1.42	1.07	0.15
VAS at 6 months	0.78	0.86	0.12
Range at 1 month	64.80	43.82	6.19
Range at 3 months	97.50	40.29	5.69
Range at 6 months	133.60	41.21	5.82
Power at 1 month	3.24	0.79	0.11
Power at 3 months	3.80	0.83	0.12
Power at 6 months	4.50	0.90	0.12

Table 4: Comparison between VAS Score at different intervals based on age

VAS Score	Age (years)		p-value
	<40 (Mean±SD)	>40 (Mean±SD)	
At Presentation	5.91±1.01	6.42±1.74	0.16
At 24 hrs	4.79±0.83	5.07±1.29	0.25
At 1 Month	2.21±1.14	2.53±1.65	0.27
At 3 Months	1.29±0.85	1.53±1.24	0.43
At 6 Months	0.62±0.64	0.92±1.01	0.42

Table 5: Comparison between power at different intervals based on age

VAS Score	Age (years)		p-value
	<40 (Mean±SD)	>40 (Mean±SD)	
(Mean±SD)			
At Presentation	1.37±0.82	1.07±1.19	0.17
At 1 Month	3.29±0.62	3.19±0.93	0.76
At 3 Months	4.00±0.78	3.61±0.85	0.10
At 6 Months	4.54±0.97	4.46±0.85	0.50

Table 6: Comparison between range of motion at different intervals based on age

Range of motion	Age (years)		p-value
	<40 (Mean±SD)	>40 (Mean±SD)	
At Presentation	18.75 ± 12.44	18.65 ± 16.15	0.77
At 1 Month	65.62 ± 41.86	64.03 ± 46.36	0.89
At 3 Months	107.91± 32.73	87.88 ± 44.68	0.19
At 6 Months	147.29± 33.45	120.96± 44.24	0.04

p<0.05 significant, Mann Whitney U-test used

between the ages of 21 and 40. Approximately 26% of study participants were in the 41-60 age range. Twenty percent of the total study participants were older than sixty years of age. Participants in the study had an average age of 43.60 years, with a standard deviation of 14.37 years. In our study, we discovered that 46% (23) of the fractures observed were radius fractures, which were subsequently followed by tibial fractures at

a rate of 24%. The remaining sites of fracture include the humerus (16%), femur (8%), and calcaneum (6%) respectively.

Table 2 display the distribution of study participants based on their fracture status after 6 months of follow-up. Our study revealed that 82% of study participants exhibited union, while 10% were observed to have malunion and 8% showed non-union.

Table 3 displays the descriptive statistics for the various parameters identified in our study. The time interval between the injury and the presentation was determined to be 2.30 hrs, with a standard deviation of 1.26 hrs. Upon evaluating the range of motion in the participants of our study, we determined that the average was 18.70 degrees, with a standard deviation of 14.35 degrees. Pain evaluation was conducted utilizing the visual analogue scale (VAS), revealing a consistent score of 6.18 among all subjects upon initial presentation.

The average VAS scores obtained at various time intervals in the study. The figure illustrates a clear declining trend in mean VAS scores as the study progresses. The mean Visual Analog Scale (VAS) score at the time of presentation was 6.18, while at 24 hrs, the mean VAS score was 4.94. The average VAS score at the 6-month follow-up was 0.78. The study observed the distribution of the mean range of motion among participants at various time intervals during follow-up.

During the presentation the mean range of motion was observed to be 18.7, while it increased to 64.8 at the one-month follow-up. The mean range of motion at the 6-month follow-up was determined to be 133.6. The line diagram displays the mean power obtained at various time intervals throughout the duration of the study. The graph clearly indicates that the mean power scores consistently rose during the follow-up period. The initial mean power at presentation was 1.22, which subsequently increased to 3.24 at the 1-month follow-up. The mean score for power at the 3-month follow-up was 3.8 and at the 6-month follow-up, it was found to be 4.5.

The $p > 0.05$, indicating statistical significance. The Mann-Whitney U test was employed. Table 4 presents a comparison of the average VAS score at various time intervals for two age groups individuals under 40 years old and individuals 40 years old or older. As a continuous dataset, normality was assessed using the Shapiro-Wilk test and it was determined that the distribution is non-parametric. The Mann Whitney U test was employed to compare the average scores between these two age groups. During the presentation, the average score for individuals under 40 years old was 5.91, while it was 6.42 for those aged 40 years and older. However, the difference in scores between the two age groups was not found to be statistically significant ($p = 0.16$). The mean VAS scores at 24 hrs for the two groups were 4.79 and 5.07, respectively. The difference between the two scores was not statistically significant ($p = 0.25$). The Mean Visual Analog Scale (VAS) scores at 1 month, 3 months, and 6 months were 2.21, 1.29 and 0.62, respectively, for individuals under the age of 40. In contrast, for individuals aged 40 and above the scores were 2.53, 1.53 and 0.92 at 1, 3 and 6 months, respectively.

The statistical analysis revealed that there was no significant difference between the two groups ($p > 0.05$).

The p-value is less than 0.05, indicating statistical significance. The Mann-Whitney U-test was employed. Table 5 presents a comparison of the mean power obtained at different follow-ups during the study between two age groups one group aged less than 40 years and another group aged 40 years or older. As a continuous dataset, normality was assessed using the Shapiro-Wilk test, which determined that the distribution was non-parametric. Mann-Whitney U-test The U-test has been employed to compare the mean scores between these two age groups. No statistically significant difference in scores between the age groups was observed at any of the follow-up intervals ($p > 0.05$). Nevertheless, the mean power exhibited a consistent increase throughout the follow-up period in both age groups.

Table 6 presents a comparison of the average range of motion observed at various follow-up intervals during the study, distinguishing between two age groups one consisting of individuals under 40 years old and the other consisting of individuals aged 40 years or older. Since the data is continuous, we assessed its normality using the Shapiro-Wilk test and determined that the distribution is non-normal. The Mann Whitney U-test was employed to compare the mean scores between these two age groups. Initially, during the presentation the average range of motion was measured to be 18.75 and 18.65 in the age groups of < 40 years and ≥ 40 years, respectively. However, the difference between these two measurements was not considered statistically significant ($p = 0.77$).

The average range of motion at one month was determined to be 64.03 inches in the age group of 40 years and older, while it was 65.62 inches in the age group younger than 40 years. Nevertheless, the disparity did not reach statistical significance ($p = 0.89$).

The average range of motion at 3 and 6 months was determined to be 107.91 and 147.29, respectively, in individuals under the age of 40. Similarly, the average range of motion in the specified age group is the values obtained at these intervals, after a period of at least 40 years, were found to be 87.88 and 120.96. The disparity between the two was not statistically noteworthy at the 3-month time interval ($p = 0.19$), but it became statistically significant at the 6-month mark ($p = 0.04$).

DISCUSSIONS

The current investigation was conducted to examine and assess the functional and radiological results of using an external fixator as a definitive and secure treatment (utilizing a minimally invasive approach) for fractures during the CORONA period.

This was achieved by evaluating the radiological condition, pain levels, range of motion and muscle strength in the treated patients. The study included 50 patients who had fractures and were treated using an external fixator, which is a minimal exposure technique, to provide definitive and safe treatment. In our study, approximately 62% of the patients were males, while the remaining 38% were females.

There are a higher proportion of males in our study, which can be attributed to males being more susceptible to injuries due to behavioral factors such as reckless driving and alcoholism. However, the finding of a higher incidence in males was not statistically significant and the occurrence was similar in both groups. Age incidence refers to the frequency or occurrence of a particular event or condition within a specific age group. Approximately 54% of the study participants in the present study fell within the age range of 21-40 years. Approximately 26% of the study participants belonged to the age group of 41-60 years.

20% of the total study participants were elderly, defined as being over 60 years old.

The average age of study participants was determined to be 43.60 years. A significant number of fractures were observed in individuals aged 21-40 years, suggesting that the younger and more active age group is more susceptible to fractures due to their behaviour and occupational factors. Bones implicated in a fracture. Our study revealed that 46% (23) of fractures observed were in the radius, followed by tibial fractures at a rate of 24%. Fractures were found in the humerus in 16% of cases, the femur in 8% of cases, and the calcaneum in 6% of cases. The majority of fractures in our study primarily affected the long bones of the upper limb, in contrast to the long bones of the lower limb. However, no significant difference was observed.

Radiological outcome: At the conclusion of the 6-month follow-up period, our study revealed that 82% of participants demonstrated successful bone union, while 10% exhibited malunion and 8% experienced non-union. In a study conducted by Dhar *et al.*^[11], it was found that 90% of the participants experienced union, while 10% experienced delayed union specifically in the lateral column. In a study conducted by Shukla *et al.*^[12] the average time for radiological union was found to be 6.2 weeks. Our study, along with other studies, demonstrates that the utilization of external fixators yields favorable outcomes among patients, as evidenced by positive radiological results during follow-up.

VAS assessment: The average VAS scores demonstrate a consistent decrease throughout the study. The mean Visual Analog Scale (VAS) score at the time of presentation was 6.18, while at 24 hrs the mean VAS score was 4.94. The mean VAS score at 6 months follow-up was 0.78. In a study conducted by

Shukla *et al.*^[13] the average pain score at 6 months follow-up was 19.17 and at 1 year follow-up it was 21.67. These scores were measured using the Green and O'Brien scoring system and they decreased over various time intervals, which was also observed in our study. Overall, the VAS scores demonstrated improvement during the follow-up period, consistent with findings from previous studies. There is no text provided. The Mean Visual Analog Scale (VAS) scores at 1 month, 3 months and 6 months were 2.21, 1.29 and 0.62, respectively, for individuals under the age of 40. In contrast, for individuals aged 40 and above the scores were 2.53, 1.53 and 0.92 at 1, 3 and 6 months, respectively. The statistical analysis revealed that the disparity between the two groups was not significant ($p > 0.05$). A study conducted by Chen *et al.*^[14] examined the Visual Analog Scale (VAS) scores of post-surgery patients in different age groups.

A study involving individuals aged 50 years or older who had unstable distal radius fractures found that the average VAS scores decreased over time. Specifically, the scores decreased from 4 at 4 weeks after surgery to 0 at 12 months after surgery. This decrease was statistically significant, with a p-value of less than 0.05. In contrast to our study findings, we did not observe a statistically significant decrease in the mean VAS score, despite observing a decrease in mean VAS scores over various follow-up time intervals. This discrepancy may be ascribed to variations in the duration of follow-up or the composition of the study population.

Range of motion: At baseline, the mean range of motion was 18.75 and 18.65 in the age groups of <40 years and ≥ 40 years, respectively. The difference between the two groups was not statistically significant ($p = 0.77$). The average range of motion at 3 and 6 months was determined to be 107.91 and 147.29, respectively, in individuals under the age of 40. Furthermore, the average range of motion for individuals aged 40 years and older was determined to be 87.88 and 120.96 at these specific time intervals, respectively. The disparity between the two was not statistically noteworthy at the 3-month time interval (0.19) but it was statistically significant at the 6-month mark ($p = 0.04$).

In a study conducted by Michael *et al.*^[15] the mean power, measured using grip strength on the Green and O'Brien scoring system, showed a statistically significant difference at 6-month and 1-year intervals ($p = 0.02$), which is consistent with our own study findings.

CONCLUSION

Our study determined that fractures can be effectively managed and treated using an external fixator as a minimally invasive procedure during the Corona period. The radiological evaluation revealed

successful fusion at the conclusion of the observation period. Assessment of VAS, range of motion, and power demonstrated improvement during the follow-up period. A larger sample size must be studied in order to conduct a comprehensive evaluation of this technique for it to be adopted as the standard approach. The potential use of an external fixator as a minimally invasive technique shows promise for restoring both range of motion and power.

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